## UNITED STATES PATENT AND TRADEMARK OFFICE

OCT 13 2009

Commissioner for Patents United States Patent and Trademark Office Alexandria VA 22313

JONES DAY 222 East 41st Street New York, NY 10017

In Re: Patent Term Extension Application for U.S. Patent No. 6,569,837

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 6,569,837 for a period of 442 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). Effective August 18, 2003, patent submissions for publication in the Orange Book and Docket \*95S-0117 need to be submitted on form FDA-3542 which may be downloaded from FDA's Electronic Forms Download Website: http://www.fda.gov/opacom/morechoices/fdaforms/default.html (http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3542.pdf).

Inquiries regarding this communication should be directed to Raul Tamayo by telephone at (571) 272-7728, or by e-mail at raul.tamayo@uspto.gov.

Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner

for Patent Examination Policy

Office of Regulatory Policy cc:

Food and Drug Administration

10903 New Hampshire Ave., Bldg. 51, Rm. 6222

Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: TYZEKA® (telbivudine)

FDA Docket No.: FDA-2007-E-0227

## UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM UNDER 35 U.S.C. § 156

(68) PATENT NO. : 6,569,837

(45) ISSUED : May 27, 2003

(75) INVENTOR : Gilles Gosselin et al.

(73) PATENT OWNER : Idenix Pharmaceuticals, Inc.; Centre National

de la Recherche Scientifique; and

L'Universite Montpellier II

(95) PRODUCT : TYZEKA® (telbivudine)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 6,569,837 based upon the regulatory review of the product TYZEKA® (telbivudine) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) 442 days

from August 10, 2019, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the United States Patent and Trademark Office to be affixed this 18th day of September 2009.

<u>2009</u>.

David J. Kappos

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office